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(54) Title: SURGICAL FASTENERS

(57) Abstract: Surgical fasteners, including tacks are disclosed for fastening a surgical mesh to underlying tissue during surgical procedures to repair body tissue, such as in hernia repair. Such tacks can include a head, a elongated body portion having a distal end and a proximal end, and an anchoring element on an outer surface of the body portion for inhibiting the removal of the tack from the mesh and body tissue.

SURGICAL FASTENERS

CROSS-REFERENCE TO RELATED APPLICATION

The present application claims priority to U.S. Provisional Application Serial No. 60/347,846 filed October 23, 2001, the entire contents of which are incorporated herein by reference.

BACKGROUND

1. Technical Field

The present disclosure relates generally to surgical fasteners for securing objects to body tissue and, more particularly, to surgical tacks for fastening a surgical mesh to underlying tissue during surgical procedures to repair body tissue, such as in hernia repair procedures.

2. Background of Related Art

In various surgical procedures, fasteners in the form of staples or the like are employed for holding tissue portions together to facilitate healing of a wound or incision. Other tissue fastening devices have been proposed and differ from staples per se in that these other devices may have a plurality of components and do not have to be clinched in the manner used to set a staple. For example, such fastening devices require access to both sides of a tissue site since they typically include an upper section having a crown and legs and a lower receiver, wherein the lower receiver engages and locks the legs of the upper section.

Although many of the above-discussed types of tissue fastening devices and techniques are satisfactory in various applications, there is a need to provide improved fastening devices which are relatively easier to apply and relatively difficult to remove.

In particular, there is a need for surgical fastening devices which do not require a second separate piece or receiver to lock, form or maintain the fastener in place in

tissue, which can be applied and secured from one side of a tissue site, most desirably in an endoscopic or open surgical procedure, and which overcome the disadvantages associated with conventional surgical staples.

5 SUMMARY

The present disclosure relates to surgical tacks primarily for fastening a surgical mesh to underlying tissue during surgical procedures to repair body tissue, such as in hernia repair procedures. In one aspect of the present disclosure, a tack for use in performing the surgical procedure includes an elongated body portion having a distal end and a proximal end, a head integrally coupled to the proximal end of the body portion and having a proximal surface and a distal surface, and an anchoring element provided on an outer surface of the body portion for inhibiting removal of the tack from body tissue.

15 It is envisioned that the anchoring element is a helical thread extending at least along a portion of the length of the body portion. Preferably, the body portion is conical, although, the body portion can be tapered such that a girth of the body portion is smaller at its distal end than at its proximal end.

The head preferably has a diameter which is larger than a diameter of the proximal end of the body portion. It is contemplated that the head includes a stackable feature, wherein the stackable feature preferably is a recess formed in the proximal surface of the head. The distal end of the body portion is atraumatic, preferably rounded. It is envisioned that the distal end of the body portion and the recess are configured and dimensioned such that the distal end of a similar tack can be seated within the recess.

25 In one embodiment, the helical thread terminates at a distance spaced from the distal surface of the head. In the same or another embodiment, the helical thread commences at a distance spaced from the distal end of the body portion.

In an embodiment, the tack can include at least one resilient prong extending from the outer surface of the body portion. The at least one resilient prong preferably is 30 disposed between the distal end of the body portion and the helical thread. Preferably,

the at least one resilient prong extends from the outer surface of the body portion from a location distally of the head.

In an embodiment, the anchoring element can include at least one resilient prong extending from an outer surface of the body portion, wherein the at least one prong has an unbiased orientation which is substantially orthogonal to a longitudinal axis of the body portion. It is contemplated that the at least one resilient prong is capable of being biased solely in a direction towards the head. Preferably, a first set of resilient prongs is provided near the distal end of the body portion and a second set of resilient prongs is provided on the body portion, proximally of the first set. It is envisioned that each set of resilient prongs includes two pair of diametrically opposed prongs. In another embodiment, the anchoring element includes at least one barb formed along on an outer surface of the body portion, preferably, at least a pair of barbs is formed along a single side of the body portion. The two pair of diametrically opposed barbs are provided near either the distal end of the body portion or near the proximal end of the body portion.

It is envisioned that the head of the tack has a rim having at least one notch formed therein.

It is contemplated that the tack is made from a biocompatible material.

In another aspect to of the present disclosure, the tack can include a backing member, at least two legs depending distally from the backing member, wherein the legs are substantially orthogonal to the backing member and are oriented in substantially the same direction as one another, and an anchoring element provided on an outer surface of each leg for inhibiting the removal of the tack from body tissue.

Preferably, the anchoring element is at least one barb extending from the outer surface of each leg. It is contemplated that each barb is oriented in a proximal direction. One of the barbs is provided near the distal end of each leg and another of the barbs is provided near a proximal end of each leg.

The backing member preferably includes at least two recesses formed in a proximal surface thereof, each recess being axially aligned with a longitudinal axis of a respective leg. The backing member preferably is elongated or annular. In one

embodiment, it is envisioned that the backing member is triangular and includes a leg depending from each respective corner of the backing member. In an embodiment, it is envisioned that the anchoring elements are barbs extending from the outer surface of each leg.

5 It is further envisioned that the backing member is elongated and that a leg depends from each respective end of the elongated member.

It is envisioned that the tack is fabricated from a bioabsorbable material.

These and other features and advantages of the present disclosure will become apparent from consideration of the following description taken in conjunction with the
10 accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

The accompanying drawings, which are incorporated and constitute a part of this specification, illustrate embodiments of the disclosure and, together with a general
15 description of the disclosure given above, and the detailed description of the embodiments given below, serve to explain the principles of the disclosure.

FIG. 1 is a side elevational view of a fastening member in accordance with the present disclosure;

FIG. 2 is a bottom plan view of the fastening member shown in FIG. 1;

20 FIG. 3 is perspective view of the fastening member shown in FIG. 1;

FIG. 4 is a perspective view of the fastening member shown in FIG. 1 illustrating one method of operation;

FIG. 5 is a perspective view of an alternate fastening member in accordance with the present disclosure;

25 FIG. 6 is a perspective view of an alternate fastening member in accordance with the present disclosure;

FIG. 7 is a perspective view of the fastening member of FIG. 6 in a stacked tip-to-tail orientation with other similar fastening members;

FIG. 8 is an illustration of the fastening member of FIG. 6 being inserted into
30 mesh;

FIG. 9 is a perspective view of an alternate fastening member in accordance with the present disclosure;

FIG. 10 is a side elevational view of an alternate fastening member in accordance with the present disclosure;

5 FIG. 10A is a bottom plan view of the fastening member shown in FIG. 10;

FIG. 11 is a side elevational view of an alternate fastening member in accordance with the present disclosure;

FIG. 11A is a bottom plan view of the fastening member shown in FIG. 11;

10 FIG. 12 is a perspective view of an alternate fastening member in accordance with the present disclosure;

FIG. 13 is a perspective view of an alternate fastening member in accordance with the present disclosure

FIG. 14 is a perspective view of an alternate fastening member in accordance with the present disclosure; and

15 FIG. 15 is a perspective view of an alternate fastening member in accordance with the present disclosure.

DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS

20 Preferred embodiments of the presently disclosed fastening members are described in detail herein with reference to the drawing figures wherein like reference numerals identify similar or identical elements. In the drawings, and in the description which follows, the term "proximal", as is traditional, will refer to the end of the fastening member which is closest to the operator, while the term "distal" will refer to the end of the fastening member which is furthest from the operator.

25 Referring now in detail to the drawing figures and, in particular initially to FIGS. 1-4, a fastening member in the form of a surgical spiral conical tack is generally shown as 10. Tack 10 includes an elongated body portion 12 having an atraumatic, here shown as rounded, distal end 14 and a head 16 provided at a proximal end thereof. Preferably, head 16 has a diameter which is larger than a proximal end of body portion
30 12. Tack 10 includes a helical thread 18 commencing from distal end 14 and

terminating at a distance "X" spaced from head 16. Head 16 is provided with at least one notch 20 formed along a rim 21 thereof. Notch 20 is preferably configured and dimensioned to be engaged by an engaging member such as a radially inwardly extending ridge 25 on the interior surface of a tubular shaft 27 of an applying tool 23 to assist in the rotation and application of tack 10 into a mesh material and underlying tissue. Head 16 also includes a stacking feature, here shown as a detent or recess 22 (see FIGS. 3 and 4) formed on a proximal surface of head 16 which is configured and adapted to receive therein a distal end 14 of another axially aligned adjacent tack 10 therein in a tip-to-tail configuration.

While tack 10 has been shown and described as having a rounded distal end 14, it is envisioned that distal end 14 of tack 10 can have any number of shapes, including and not limited to sharpened, conical, blunt, triad, helical/spiral or the like. Further, it is envisioned that while a body portion 12 is preferably conical, tack 10 can be formed having a tapered or substantially cylindrical body portion. In addition, body portion 12 can be provided with a longitudinal lumen or passage (not shown) which is co-axial with a longitudinal axis of tack 10. Preferably, body portion 12 of tack 10 is tapered such that body portion 12 has a girth which is smaller at distal end 14 than at the proximal end thereof.

An exemplary method of use of tack 10, in a hernia repair procedure, initially requires the use of conventional surgical techniques to prepare the hernia site within the patient's abdominal cavity and to place a conventional piece of biocompatible surgical mesh over the hernia site itself. A distal end of an applying tool, having at least one, usually a plurality of tacks 10 operatively associated with tool 23, is advanced into close proximity with and applied to the surface of the surgical mesh until helical thread 18 of a tack engages the surgical mesh. The applying tool is then used to rotate tack 10 which causes tack 10 to be drawn distally through the surgical mesh and into the tissue preferably until and so that the bottom surface of head 16 contacts the mesh. The process is repeated as many times as deemed necessary in order to secure the surgical mesh to the underlying tissue. For complete insertion of body portion 12 of tack 10 through the surgical mesh and into the body tissue it is preferred that helical thread 18

pass completely through the surgical mesh. If body portion 12 is inserted in that manner, tack 10 is prevented from coming free or backing out through the surgical mesh due to the abutment of the proximal end of helical thread 18 against the inner surface of the surgical mesh.

- 5 Turning now to FIG. 5, an alternative embodiment of a fastening member, in the form of a tack, is shown generally as 10a. In the present embodiment, helical thread 18 commences from a distance "Y" spaced from distal end 14 and terminates at a distance "X" spaced from head 16. According to the present embodiment, tack 10a is further provided with a plurality of radially extending resilient prongs 24 disposed between a
- 10 distal end of helical thread 18 and distal end 14 of body portion 12. Preferably, resilient prongs 24 are capable of being deflected in proximal directions including in angular and arcuate or circumferential directions relative to elongated body portion 12. In use, tack 10a is inserted into the body tissue preferably by first pressing/pushing tack 10a distally and with little or no rotation through the surgical mesh, thereby deflecting
- 15 resilient prongs 24 in a proximal direction, until helical thread 18 engages the surgical mesh. The applying tool is then used to rotate tack 10a which causes tack 10a to continue to move distally through the surgical mesh and into the tissue until the bottom surface of head 16 contacts the mesh. Upon rotation of tack 10a resilient prongs 24 deflect in angular and arcuate or circumferential directions relative to elongated body
- 20 portion 12. In this embodiment, tack 10a is prevented from backing out due to the joint cooperation of helical thread 18 (as described above with regard to tack 10) and due to resilient prongs 24 (now at least partially oriented in a proximal direction) acting as anchors and that engage and are retained by the body tissue.

- As seen in FIGS. 6-8, an alternative embodiment of a fastening member, in the
- 25 form of a tack, is shown generally as 10b. Tack 10b includes a distal set of resilient prongs 26 extending radially from body portion 12 and a proximal set of resilient prongs 28 also extending radially from body portion 12. Preferably, distal prongs 26 are located proximate to and spaced a distance from distal end 14, while prongs 28 are located proximally of prongs 26 and, as here shown, spaced a distance from head 16.
- 30 Prongs 26 and 28 are preferably capable of being deflected in a proximal direction,

desirably toward head 16. Preferably, the prongs of a set are diametrically opposed to each other and axially aligned with the prongs of the other set.

In use, as seen in FIG. 8, as tack 10b is pressed through a surgical mesh "M", prongs 26 and 28 bend back (i.e., in a proximal direction) near or more preferably against body portion 12 allowing body portion 12 of tack 10b to pass through mesh "M". Once prongs 26 and 28 pass completely through mesh "M" and tack 10b is completely imbedded into underlying body tissue "T", preferably prongs 26 and 28 return to a substantially transverse orientation with respect to body portion 12, thus preventing tack 10b from being pulled back out through mesh "M". As seen in FIG. 7, a plurality of tacks 10b can be aligned and stacked in tip-to-tail fashion with one another by an engagement or placement of distal end 14 of body portion 12 in recess 22 formed in head 16. It is desirable to stack tacks of the disclosure in tip-to-tail fashion when a plurality of tacks are loaded directly into an applying tool or into a cartridge assembly which is later coupled to an insertion tool. Here, distal set of prongs 26 help to stabilize the upper tack relative to the underlying tack.

FIG. 9 shows an alternative embodiment, a tack 10b', whose body portion 12 has a single pair of diametrically opposed resilient barbs 30. Barbs 30 are preferably oriented in a proximal direction wherein a distal end of each barb 30 is spaced a distance from body portion 12. Since barbs 30 are so oriented, insertion of tack 10b into body tissue is facilitated while removal of tack 10b from the body tissue is impeded by the anchoring effect of barbs 30 engaging into the body tissue.

While the shape of prongs 24, 26 and 28 have been shown throughout the figures as being substantially cylindrical in cross-section and having a certain length, it is envisioned that prongs 24, 26 and 28 can have a cross-sectional profile of any shape, including and not limited to, rectangular, triangular, polygonal, elliptical and the like. It is further envisioned that prongs 24, 26 and 28 can have any desired length as deemed necessary for the particular surgical procedure in which they are going to be used.

In FIGS. 10-11A, alternate embodiments of fastening members, in the form of tacks, are generally shown as 100. As seen in FIGS. 10 and 10A, tack 100 includes a

head 104 and a body portion 102 having upper and lower sets of radially extending preferably rigid barbs 106a, 106b, extending radially from body portion 102. As shown, preferably the barbs of each pair are diametrically opposed, and the barbs of the pairs are axially aligned. In an alternative configuration, as seen in FIGS. 11-11A, tack 5 100a is provided with a single upper barb 106a and a single lower barb 106b. Barbs 106a, 106b are formed along one side of leg 102. It is envisioned that any number of barbs 106 can be provided along the outer surface of leg 102. Moreover, barbs 106 can be oriented in any radial direction relative to one another.

Turning now to FIGS. 12-14, an alternative fastening member, here shown in the form of a tack generally depicted 200. As seen in FIG. 12, tack 200 includes an elongated backing member 202 having a leg 204 depending from each end thereof. Preferably, each leg 204 is substantially orthogonal with respect to an axis defined by backing member 202. Legs 204 are preferably substantially oriented in the same direction as one another. Each leg 204 is provided with a substantially oriented 15 resilient barb 206 formed at a distal end thereof. Preferably, the terminal end of each barb 206 is spaced from the leg 204 from which it extends. While, as seen in FIG. 12, it is preferred that barbs of the tacks of the disclosure, for example, here 206, are directed or generally oriented toward one another, it is envisioned that barbs 206 can be disposed in any radial and/or proximal direction anywhere about each leg 204. Backing 20 member 202 preferably is provided with a pair of recesses 208 formed in a proximal surface thereof. Preferably, recesses 208 are axially aligned with a longitudinal axis of a respective leg 204 and are configured and adapted to receive the distal ends of respective legs 204 from an adjacent tack 200. In an alternative embodiment, shown in FIG. 13, each leg 204 of tack 200 includes a pair of barbs 206. Preferably, barbs 206 of 25 each leg 204 are oriented directly or generally towards each other.

In yet another embodiment, shown in FIG. 14, tack 200b includes a backing member 202 that is annular and is defined by a single, a pair or by a plurality of arcuate backing members 202a and 202b. Annular backing-member 202 defines an opening 210 therethrough which can be for receiving a shaft of an insertion tool therethrough.

Backing-member 202 further includes a pair of recesses 208 formed in a proximal

surface thereof, which recesses 208 are axially aligned with a longitudinal axis of a respective leg 204. The recess(es) in the backing member(s) of the tacks of the disclosure can be configured for stacking and/or application purposes.

FIG. 15 shows an alternative embodiment of a fastening member, in the form of a tack, generally shown as 300. Tack 300 includes a triangular head 302 having a leg 304 depending from each corner 306 thereof. Each leg 304 is provided with at least one barb 308 formed on and preferably along a portion of the length thereof, preferably, at or near a distal tip thereof. It is envisioned that barbs 308 are oriented in a direction facing substantially toward a center of head portion 302.

An exemplary method of use of the tacks disclosed herein (hereinafter, for simplicity, "tack 100") in a hernia repair procedure will now be described. The hernia site in the patient's abdominal cavity is first prepared using conventional surgical techniques and a conventional piece of biocompatible surgical mesh is placed over the hernia site, understood to include tissue or body portions surrounding the hernia. Next, tack 100 is applied by a tack applier, or by grasping tack 100 with an appropriate grasping instrument and placing the tack into position proximate to the tissue to be fastened. Preferably, the tack is positioned such that the legs are oriented substantially perpendicular to the surface of the tissue. Tack 100 is then pushed distally until its distal ends penetrate the mesh and the underlying tissue, preferably until the distal surface of the head contacts the surface of the surgical mesh. The procedure is repeated as many times with as many tacks as deemed necessary to secure the mesh to the underlying tissue.

Although this disclosure has been shown and described with respect to detailed embodiments thereof, it will be understood by those skilled in the art that various changes in form and detail thereof may be made without departing from the spirit and scope of the disclosure.

For example, preferably, the head of each fastening member is flattened to reduce interference with or reduce trauma to the body. While a flattened head is preferred, it is contemplated that the head can take on any configuration, including and not limited to arcuate, hemispherical, rectangular or the like.

The fastening members of the present disclosure may be manufactured from biocompatible absorbable or non-absorbable (i.e., stainless steel, titanium, polymers, composites and the like and equivalent) materials. It is particularly preferred that the fastening members of the present disclosure are manufactured from absorbable

5 materials which are absorbed into the body over the course of the healing process thereby eliminating the existence of the fastener after it is no longer needed to perform its function of approximating or fastening tissue or body matter. Examples of absorbable materials include homopolymers and copolymers of lactide, glycolide, trimethylene carbonate, caprolactone, and p-dioxanone and blends thereof.

- 10 From the foregoing, it will be observed that numerous variations and modifications may be effected without departing from the true spirit and scope of the novel concepts of the disclosure. Further, it is to be understood that no limitation with respect to the specific articles, instruments and methods disclosed herein is intended or should be inferred.

WHAT IS CLAIMED IS:

1. A tack for use in a surgical procedure, the tack comprising:
an elongated body portion having a distal end and a proximal end;
a head integrally coupled to the proximal end of the body portion and having a
5 proximal surface and a distal surface; and
an anchoring element provided on an outer surface of the body portion for
inhibiting the removal of the tack from body tissue.
2. The tack according to claim 1, wherein the anchoring element is a
10 helical thread extending at least along a portion of the length of the body portion.
3. The tack according to claim 2, wherein the body portion is conical.
4. The tack according to claim 2, wherein the body portion is tapered such
15 that a girth of the body portion is smaller at its distal end than at its proximal end.
5. The tack according to claim 2, wherein the head has a diameter which is
larger than a diameter of the proximal end of the body portion.
- 20 6. The tack according to claim 5, wherein the head includes a stackable
feature.
7. The tack according to claim 6, wherein the stackable feature is a recess
formed in the proximal surface of the head.
- 25 8. The tack according to claim 2, wherein the distal end of the body portion
is atraumatic.
9. The tack according to claim 8, wherein the distal end is rounded.

10. The tack according to claim 2, wherein the distal end of the body portion and the recess are configured and dimensioned such that the distal end of a similar tack can be seated within the recess.

5 11. The tack according to claim 2, wherein the helical thread terminates at a distance spaced from the distal surface of the head.

12. The tack according to claim 11, wherein the helical thread commences at a distance spaced from the distal end of the body portion.

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13. The tack according to claim 2, wherein the head has a rim having at least one notch formed therein.

14. The tack according to claim 2, further including at least one resilient
15 prong extending from the outer surface of the body portion.

15. The tack according to claim 14, wherein the at least one resilient prong is disposed between the distal end of the body portion and the helical thread.

20 16. The tack according to claim 12, further including at least one resilient prong extending from the outer surface of the body portion from a location distally of the head.

25 17. The tack according to claim 1, wherein the anchoring element is at least one resilient prong extending from an outer surface of the body portion, wherein the at least one prong has an unbiased orientation which is substantially orthogonal to a longitudinal axis of the body portion.

30 18. The tack according to claim 17, wherein the at least one resilient prong is capable of being biased solely in a direction towards the head.

19. The tack according to claim 18, wherein a first set of resilient prongs is provided near the distal end of the body portion and a second set of resilient prongs is provided on the body portion, proximally of the first set.

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20. The tack according to claim 19, wherein each set of resilient prongs includes two pair of diametrically opposed prongs.

21. The tack according to claim 1, wherein the anchoring element includes
10 at least one barb formed on an outer surface of the body portion.

22. The tack according to claim 21, wherein at least a pair of barbs is formed along a single side of the body portion.

23. The tack according to claim 18, wherein two pair of diametrically
15 opposed barbs are provided near the distal end of the body portion.

24. The tack according to claim 18, wherein two pair of diametrically
20 opposed barbs are provided near the proximal end of the body portion.

25. The tack according to claim 1, wherein the tack is made from a biocompatible material.

26. A tack for use in a surgical procedure, the tack comprising:
25 a backing member;
at least two legs depending distally from the backing member, wherein the legs are substantially orthogonal to the backing member and are oriented in substantially the same direction as one another; and
an anchoring element is provided on an outer surface of each leg for inhibiting
30 the removal of the tack from body tissue.

27. The tack according to claim 26, wherein the anchoring elements are barbs extending from the outer surface of each leg.

5 28. The tack according to claim 27, wherein each barb is oriented in a proximal direction.

29. The tack according to claim 28, wherein one of the barbs is provided near the distal end of each respective leg and another of the barbs is provided near a
10 proximal end of each respective leg.

30. The tack according to claim 26, wherein the backing member includes at least two recesses formed in a proximal surface thereof, each recess being axially aligned with a longitudinal axis of a respective leg.

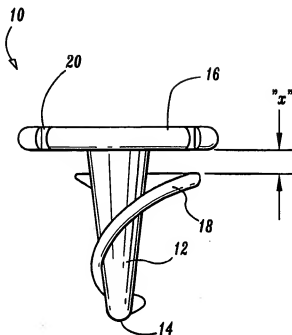
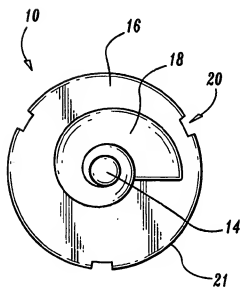
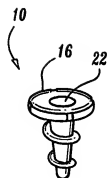
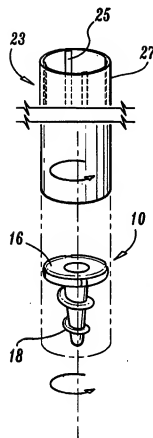
15 31. The tack according to claim 26, wherein the tack is fabricated from a bioabsorbable material.

32. The tack according to claim 31, wherein the backing member is annular
20 and has an opening therethrough.

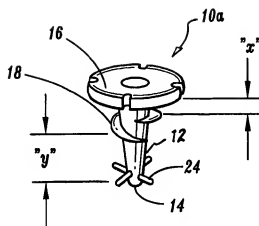
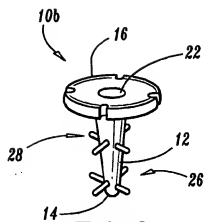
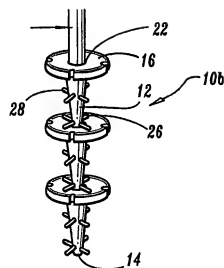
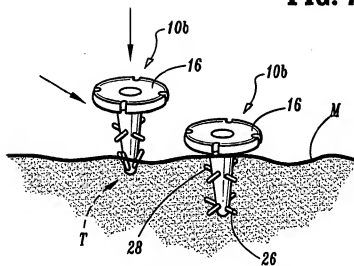
33. The tack according to claim 31, wherein the backing member is triangular and includes a leg depending from each corner of the backing member.

25 34. The tack according to claim 33, wherein the backing member is triangular and includes a leg depending from each corner of the backing member and wherein the anchoring element is a barb extending from the outer surface of each leg.

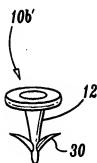
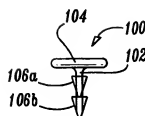
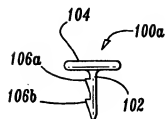
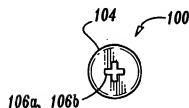
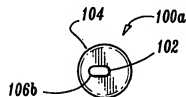
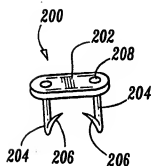
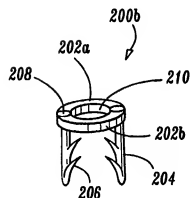
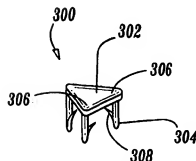
30 35. The tack according to claim 31, wherein the backing member is elongated and a leg depends from each respective end of the elongated member.

**FIG. 1****FIG. 2****FIG. 3****FIG. 4**

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**FIG. 5****FIG. 6****FIG. 7****FIG. 8**

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**FIG. 9****FIG. 10****FIG. 11****FIG. 10A****FIG. 11A****FIG. 12****FIG. 13****FIG. 14****FIG. 15**